

PATENT
ATTORNEY DOCKET NO.: SSK-50(18583)

UNITED STATES PATENT APPLICATION

ENTITLED

METHOD FOR FORMING AN ELASTOMERIC ARTICLE

BY

SHANTI MODHA

MARY KISTER

AND

K.C. NGUYEN

METHOD FOR FORMING AN ELASTOMERIC ARTICLE**Background of the Invention**

Elastomeric gloves, such as surgical and examination gloves, have traditionally been made of natural or synthetic elastomers to provide a combination of good elasticity and strength. To form a natural rubber glove, for instance, a hand-shaped former is initially dipped into a coagulant composition and subsequently into a natural rubber latex bath. The coagulant causes the latex to deposit on the former. The coagulant composition may include a salt, such as calcium carbonate or calcium nitrate, which facilitates the formation of an elastomeric polymer into a substrate body and aids in removal of the tacky polymer from the former. Surfactants may also be used in the coagulant composition.

Once formed, the latex substrate body is then subjected to various treatment processes to improve its properties. For example, due to the tight fit of elastomeric gloves over the hand, they are often difficult to don. As a result, various techniques have been developed to aid in the donnability of elastomeric gloves. Many conventional treatment steps require the glove to be stripped from the former used in the "on-line" glove-forming process, and sent "off-line" for the desired post-treatment. For example, gloves are often lubricated off-line in a tumbler. To strip the glove from the former for such off-line processing, it is typically necessary to apply an antiblocking powder to the outer surface of the substrate body (facing away from the former), such as calcium carbonate, calcium stearate, magnesium carbonate, and so forth, which inhibits the glove from sticking to itself when stripped. For example, prior to stripping, the former may be dipped into a slurry that contains the antiblocking powder. Unfortunately, the use of such powders has many drawbacks in the manufacture of some types of gloves, such as those used in surgical or clean room environments. For example, powder may enter a wound and cause complications for the patient. Powder may also carry infectious agents and/or cause allergenic reactions in the patient. Thus, several techniques have been developed to remove antiblocking powders from gloves. For example, gloves may be chlorinated "off-line" using well-known techniques (e.g., a chlorinator) to remove the antiblocking powder prior to use of the glove.

Despite the benefits achieved using conventional glove-forming processes, a need for improvement nevertheless remains. Specifically, the requirement of

various "off-line" post-treatment steps is time-consuming, costly, and inefficient. Thus, a need continues to remain for a method of forming a glove in a more efficient and cost-effective manner.

Summary of the Invention

- 5 In accordance with one embodiment of the present invention, a method for forming an elastomeric glove is disclosed. The method comprises:
- dipping a hand-shaped former into at least one bath containing an elastomeric material to form a substrate body, the substrate body having an inner surface and an outer surface that define a hand-shaped cavity, the inner surface being positioned adjacent to the hand-shaped former;
- 10 applying a hydrogel coating to the outer surface of the substrate body while the inner surface of the substrate body remains adjacent to the hand-shaped former, wherein the hydrogel coating has a thickness of from about 0.1 to about 20 micrometers; and
- 15 thereafter, stripping the glove from the hand-shaped former without the use of an antiblocking powder, wherein the glove is inverted so that the outer surface of the substrate body applied with the hydrogel coating is configured to face a user's hand when inserted into the hand-shaped cavity.
- 20 In accordance with another embodiment of the present invention, a method for forming an elastomeric article is disclosed. The method comprises:
- dipping a former into at least one bath containing an elastomeric material to form a substrate body, wherein the elastomeric material of the substrate body includes natural rubber latex, the substrate body having an inner surface and an outer surface that define a cavity, the inner surface being positioned adjacent to the former;
- 25 applying a hydrogel coating and a lubricant coating to the outer surface of the substrate body while the inner surface of the substrate body remains adjacent to the former; and
- 30 thereafter, stripping the elastomeric article from the former without the use of an antiblocking powder, wherein the elastomeric article is inverted so that the outer surface of the substrate body applied with the hydrogel coating and the lubricant coating is configured to face a user's skin when inserted into the cavity.
- In accordance with still another embodiment of the present invention, a

method for forming an elastomeric glove is disclosed. The method comprises:

dipping a hand-shaped former into at least one bath containing an elastomeric material to form a substrate body, the substrate body having an inner surface and an outer surface that define a hand-shaped cavity, the inner surface being positioned adjacent to the hand-shaped former;

5 applying a hydrogel coating and a lubricant coating to the outer surface of the substrate body while the inner surface of the substrate body remains adjacent to the hand-shaped former, wherein the hydrogel coating is formed from a monomer selected from the group consisting of hydroxyethyl acrylates, hydroxyethyl methacrylates, hydroxypropyl acrylates, derivatives thereof, and combinations thereof; and

10 thereafter, stripping the glove from the hand-shaped former without the use of an antiblocking powder, wherein the glove is inverted so that the outer surface of the substrate body applied with the hydrogel coating is configured to face a user's hand when inserted into the hand-shaped cavity.

15 Other features and aspects of the present invention are discussed in greater detail below.

Brief Description of the Drawings

A full and enabling disclosure of the present invention, including the best mode thereof, directed to one of ordinary skill in the art, is set forth more particularly in the remainder of the specification, which makes reference to the appended figures in which:

20 Fig. 1 is a perspective view of one embodiment of an elastomeric glove made according to the invention; and

25 Fig. 2 is a cross-sectional view of the glove illustrated in Fig. 1 taken along a line 2-2.

Repeat use of reference characters in the present specification and drawings is intended to represent same or analogous features or elements of the invention.

Detailed Description of Representative Embodiments

30 Reference now will be made in detail to various embodiments of the invention, one or more examples of which are set forth below. Each example is provided by way of explanation of the invention, not limitation of the invention. In

fact, it will be apparent to those skilled in the art that various modifications and variations may be made in the present invention without departing from the scope or spirit of the invention. For instance, features illustrated or described as part of one embodiment, may be used on another embodiment to yield a still further 5 embodiment. Thus, it is intended that the present invention covers such modifications and variations as come within the scope of the appended claims and their equivalents.

In general, the present invention is directed to an elastomeric article (e.g., glove, condom, and so forth) that is coated with a hydrogel. The hydrogel coating 10 facilitates dry and/or damp donning. In addition, due its low coefficient of friction, the hydrogel allows stripping of a dip-formed article without the use of an antiblocking powder. Thus, the present inventors have discovered that certain treatment steps, such as chlorination and/or lubrication, conventionally conducted 15 "off-line" (i.e., after stripping) are no longer required. Moreover, even when such treatments are used, they may be conducted "on-line" (i.e., before stripping). The ability to eliminate certain off-line treatment steps provides a significant 20 improvement in the efficiency of the forming process.

Referring to Figs. 1-2, for example, one embodiment of an elastomeric glove 20 is illustrated that may be placed on the hand of a user 22. The glove 20 includes a substrate body 24 having the basic shape of the glove, e.g., having an inner surface and an outer surface that define a hand-shaped cavity. The substrate body 24 is generally formed from an emulsion-based elastomeric 25 material (e.g., polymers formed by emulsion polymerization). Some examples of materials that be used to form the emulsion-based elastomeric material include, but are not limited to, natural rubber latex, isoprene polymers, chloroprene polymers, vinyl chloride polymers, butadiene polymers, styrene-butadiene polymers, carboxylated styrene-butadiene polymers, acrylonitrile-butadiene polymers, carboxylated acrylonitrile-butadiene polymers, acrylonitrile-styrene-butadiene polymers, carboxylated acrylonitrile-styrene-butadiene polymers, derivatives thereof, and so forth. Combinations of elastomeric materials may also 30 be used in a single layer of an article or in separate layers, such as in a multi-layer article.

In one embodiment, the substrate body 24 is formed from natural rubber

latex. To form the substrate body 24 from natural latex, a former is initially dipped into a coagulant bath that facilitates later stripping of the glove from the former.

The coagulant bath may include calcium carbonate and/or calcium nitrate.

Thereafter, the coagulant-coated former is dried and subsequently dipped into one or more latex baths. The resulting latex layer(s) are then typically leached in water to extract a large percentage of the water-soluble impurities in the latex and coagulant. The coated former is then dried to cure (i.e., crosslink) the rubber. It should be understood that the conditions, process, and materials used in forming natural rubber gloves are well known in the art, and are not critical to the practice of the present invention.

Regardless of the particular material used to form the substrate body 24, the glove 20 includes a hydrogel coating 26 that is present on an inner surface 28 defined by the substrate body 24. The hydrogel coating 26 has a low coefficient of friction that facilitates donning of the glove 20 when the user's hand is either dry or wet, i.e., dry or damp donning. The low coefficient of friction may be imparted through surface texture and/or through the lubricity of the materials used to form the hydrogel coating 26. In addition to facilitating donning, another purpose of the hydrogel coating 26 is to allow stripping of the glove from a former without the use of an antiblocking powder. Specifically, the hydrogel coating 26 blocks the surface of the tacky substrate body 24, thereby preventing it from sticking to itself. Consequently, the glove 20 may be stripped from a former without fear of sticking of the substrate body 24.

Generally speaking, any of a variety of polymers may be utilized in the present invention to form the hydrogel coating 26. Such polymers are formed from at least one hydrogel-forming monomer that is hydrophilic and water-soluble. There are many known hydrophilic, water-soluble monomers that may be used in the present invention to form the hydrogel polymer. Some examples of such monomers include, but are not limited to, vinyl pyrrolidone, hydroxyethyl acrylate or methacrylate (e.g., 2-hydroxyethyl methacrylate), hydroxypropyl acrylate or methacrylate, acrylic or methacrylic acid, acrylic or methacrylic esters or vinyl pyridine, acrylamide, vinyl alcohol, ethylene oxide, derivatives thereof, and so forth. Other examples of suitable monomers are described in U.S. Patent Nos. 4,499,154 to James, et al., which is incorporated herein in its entirety by reference

thereto for all purposes. The resulting polymers may be homopolymers or interpolymers (e.g., copolymer, terpolymer, etc.), and may be nonionic, anionic, cationic, or amphoteric. In addition, the polymer may be of one type (i.e., homogeneous), or mixtures of different polymers may be used (i.e., heterogeneous).

5

To form the hydrogel coating 26, the polymer(s) are crosslinked using any known crosslinking technique, including known ionic or covalent crosslinking techniques. For example, in some embodiments, a crosslinking agent may be utilized to facilitate crosslinking. Examples of crosslinking agents include, but are 10 not limited to, polyhydric alcohols (e.g., glycerol); polyaziridine compounds (e.g., 2,2-bishydroxymethyl butanoltris[3-(1-aziridine) propionate] or triaziridine); epoxy compounds; haloepoxy compounds (e.g., epicholorhydrin); aldehyde compounds (e.g., urea-formaldehyde, melamine-formaldehyde, hydantoin-formaldehyde, glutaraldehyde, glyoxal, malonaldehyde, succinaldehyde, adipaldehyde, or dialdehyde starch); polyisocyanate compounds (e.g., 2,4-toluene diisocyanate); etc. Crosslinking may be carried out before, during, and/or after application of the polymer to the surface 28 of the substrate body 24. For example, in one 15 embodiment, an aqueous solution containing a crosslinking agent and polymer is applied to the surface 28. Thereafter, the mixture is cured at elevated temperatures. Besides thermal activation, crosslinking may also be carried out using other well-known techniques. For example, crosslinking may be induced with ionizing radiation, which is radiation having an energy sufficient to either directly or indirectly produce ions in a medium. Some suitable examples of 20 ionizing radiation that may be used in the present invention include, but are not limited to, electron beam radiation, natural and artificial radio isotopes (e.g., α , β , and γ rays), x-rays, neutron beams, positively charged beams, laser beams, and so forth. Electron beam radiation, for instance, involves the production of 25 accelerated electrons by an electron beam device. Electron beam devices are generally well known in the art. For instance, in one embodiment, an electron beam device may be used that is available from Energy Sciences, Inc., of Woburn, Massachusetts under the name "Microbeam LV." Other examples of suitable 30 electron beam devices are described in U.S. Patent Nos. 5,003,178 to Livesay; 5,962,995 to Avnery; 6,407,492 to Avnery, et al., which are incorporated herein in

their entirety by reference thereto for all purposes.

Regardless of the technique utilized, crosslinking forms a hydrogel constituted by a three-dimensional network that is substantially water-insoluble. Thus, when exposed to water, the hydrogel does not dissolve, but instead may absorb a certain amount of water. For example, the hydrogel is capable of achieving a water content of from about 20% to about 90%, in some embodiments from about 35% to about 85%, and in some embodiments, from about 50% to about 80%. The water content of the hydrogel is determined as follows:

$$\text{10} \quad \% \text{ water} = 100 \times \frac{(\text{weight of wet hydrogel} - \text{weight of dry hydrogel})}{\text{weight of wet hydrogel}}$$

Besides facilitating donning and allowing stripping of the glove 20 without an antblocking powder, the hydrogel coating 26 also provides other unexpected benefits. For instance, upon absorbing water, the hydrogel coating 26 swells, thereby increasing the area between crosslinks to form pores. For example, at its highest water content, the hydrogel coating 26 may possess pores having an average size of from about 1 nanometer to about 10 microns, in some embodiments from about 10 nanometers to about 1 micron, and in some embodiments, from about 50 nanometers to about 100 nanometers.

Due to its ability to swell in the above-described manner, an active agent may be incorporated into the hydrogel coating 26 that is controllably releasable therefrom to impart some benefit to a user 22. Specifically, the expected conditions of use expose the hydrogel coating 26 to moisture from a variety of sources, such as water present on a user's hand from washing, moisture secreted by mammalian sweat glands, and so forth. For instance, human sweat glands are of two types, eccrine and apocrine. The apocrine glands occur only in the armpits and about the ears, nipples, navel, and anogenital region, are scent glands. Eccrine glands, however, are present throughout the body, including the hands, and are designed to regulate the temperature of the body. Obviously, the amount of fluid secreted by the eccrine glands depends on body temperature; however, even on cold days, some transepidermal water loss will likely occur. Because elastomeric gloves (e.g., surgical gloves) often fit tightly over a user's hand and do not allow outside air to readily cool the skin, the temperature of the user's hand is

likely to increase when wearing the glove. This temperature increase may also cause additional fluid to be secreted by the eccrine glands.

Thus, when placed adjacent to a user's skin, the hydrogel coating 26 will invariably be exposed to fluids secreted by eccrine glands or from some other source. This exposure leads to an increase degree of hydration for the hydrogel coating 26 and a corresponding increase in the size of its pores. As the pore size increases, an active agent within the crosslinked hydrogel network may be released. Once released, the active agent may interact directly with epithelial tissue at the cellular level to provide a benefit to the skin. Alternatively, the active agent may interact with components at or near the skin surface to provide the desired benefit.

The active agent may be incorporated into the hydrogel coating 26 before, during, and/or after its formation. In one embodiment, for example, the active agent may be mixed with the hydrogel-forming polymer and crosslinking agent prior to crosslinking. When crosslinked, the active agent is retained within the three-dimensional network. As stated, the active agent may also be applied after formation of the hydrogel. For example, the hydrogel coating 26 may be applied with an aqueous solution containing the active agent. As described above, the aqueous solution hydrates the hydrogel coating 26 and causes an increase in porosity. Due to this increased porosity, the active agent may diffuse through the pores and into the crosslinked hydrogel network. The hydrogel coating 26 is subsequently dried to retain the active agent therein. Typically, the size of the active agent is smaller than the pore size of the hydrogel when dry so that it remains physically retained within the hydrogel network. Apart from being physically retained within the hydrogel coating 26, the active agent may also be chemically bonded to the hydrogel, such as through covalent, ionic, or hydrogen bonding.

Generally speaking, the "active agent" may be any compound or mixture thereof that may produce a desired result. Whether in solid or liquid form, the active agent typically possesses a sufficient solubility or miscibility in an aqueous system to render it capable of being released through the pores of the crosslinked hydrogel network. Examples of such active agents include, but are not limited to, drugs, skin-conditioners, botanical agents, etc. "Drugs" include any physiologically

or pharmacologically active substance that produces a localized or a systemic effect in animals. The drugs that may be delivered include, but are not limited to, anti-inflammatory agents, immunosuppressives, antimicrobials, anesthetics, analgesics, hormones, antihistamines, and so forth. Numerous such compounds are known to those of skill in the art and described, for example, in The Pharmacological Basis of Therapeutics, Hardman, Limbird, Goodman & Gilman, McGraw-Hill, New York, (1996), as well as U.S. Patent Nos. 6,419,913 to Niemiec, et al.; 6,562,363 to Mantelle, et al.; 6,593,292 to Rothbard, et al.; 6,567,693 to Allen, Jr.; and 6,645,181 to Lavi, et al., all of which are incorporated herein in their entirety by reference thereto for all purposes. Although several examples of active agents are described herein, it should be understood that the present invention is by no means limited to any particular active agent. In fact, any active agent having any benefit whatsoever to a user may be utilized in accordance with the present invention.

In this regard, one class of suitable drugs includes anti-inflammatory agents, such as glucocorticoids (adrenocorticoid steroids). Exemplary glucocorticoids include, for example, hydrocortisone, prenisone (deltasone) and predrisonlone (hydeltasol). Glucocorticoids may be used to treat inflammatory skin diseases, such as eczema (e.g., atopic dermatitis, contact dermatitis, and allergic dermatitis), bullous disease, collagen vascular diseases, sarcoidosis, Sweet's disease, pyoderma gangrenosum, Type I reactive leprosy, capillary hemangiomas, lichen planus, exfoliative dermatitis, erythema nodosum, hormonal abnormalities (including acne and hirsutism), toxic epidermal necrolysis, erythema multiforme, cutaneous T-cell lymphoma, discoid lupus erythematosus, and so forth. Retinoids, such as retinol, tretinoiin, isotretinoiin, etretinate, acitretin, and arotinoid, may also be used. Conditions that are possibly treatable using retinoids include, but are not limited to, acne, keratinization disorders, psoriasis, cutaneous aging, discoid lupus erythematosus, scleromyxedema, verrucous epidermal nevus, subcorneal pustular dermatosis, Reiter's syndrome, warts, lichen planus, acanthosis nigricans, sarcoidosis, Grover's disease, porokeratosis, and so forth. Other suitable anti-inflammatory drugs are COX-2 inhibitors, such as celecoxib, meloxicam, rofecoxib, and flosulide. These drugs inhibit the production of the COX-2 (cyclooxygenase-2) enzyme induced by pro-inflammatory stimuli in migratory cells and inflamed tissue.

In addition, nonsteroidal anti-inflammatory drugs (NSAIDs) may also be utilized. Examples of NSAIDs include, but are not limited to, Aspirin, Ibuprofen, Indomethacin, Phenylbutazone, Bromfenac, Sulindac, Nabumetone, Ketorolac, Mefenamic Acid, and Naproxen.

5 Immunosuppressive drugs constitute an additional class of drugs from which the active agent may be selected. These drugs may be used to treat hyperproliferative diseases, such as psoriasis, as well as immune diseases, such as bullous dermatoses and leukocytoclastic vasculitis. Examples of such drugs include, but are not limited to, antimetabolites, such as methotrexate, azathioprine, 10 fluorouracil, hydroxyurea, 6-thioquanine, mycophenolate, chlorambucil, vinicristine, vinblasrine and dactinomycin; alkylating agents, such as cyclophosphamide, mechloroethamine hydrochloride, carmustine, taxol, tacrolimus and vinblastine; and so forth.

15 Another class of suitable drugs includes antimicrobial agents, e.g., antibacterial, antifungal, antiviral, etc. Antibacterial agents are useful for treating conditions such as acne, cutaneous infections, and so forth. For instance, some suitable antimicrobial agents include, but are not limited to, bisphenols, such as 2,4,4'-trichloro-2'-hydroxydiphenyl ether (triclosan); quaternary ammonium compounds, such as benzalkonium chloride; esters of parahydroxy benzoic acid, 20 such as methyl parabens; formaldehyde and formaldehyde donors, such as 2-bromo-2-nitro-1,3 propanediol, hydantoins, diazolidinyl urea, and imidazolidinyl urea; alkylisothizaolinones; phenoxyethanol; chlorhexidine gluconate; parachlorometaxylenol (PCMX); chitosan, such as chitosan pyrrolidone carboxylate; combinations thereof, and so forth. Antifungal agents may also be 25 used to treat conditions, such as tinea corporis, tinea pedis, onychomycosis, candidiasis, tinea versicolor, onychomycosis, and so forth. Examples of antifungal agents include, but are not limited to,azole antifungals such as itraconazole, myconazole and fluconazole. Examples of antiviral agents include, but are not limited to, acyclovir, famciclovir, and valacyclovir. Such agents are useful for 30 treating viral diseases, such as herpes.

Antihistamines are still another class of suitable drugs. Examples of such antihistamines include, for example, terfenadine, astemizole, loratadine, cetirizine, acrivastine, temelastine, cimetidine, ranitidine, famotidine, nizatidine, and so forth.

These agents may be used to treat conditions such as pruritus, atopic dermatitis, contact dermatitis, psoriasis, etc. Further, local anesthetics constitute another class of drugs that may be used. Examples of such local anesthetics include, but are not limited to, lidocaine, bupivacaine, novocaine, procaine, tetracaine, benzocaine, mepivacaine, etidocaine, 2-chloroprocaine hydrochloride, and so forth.

Other than drugs, various other active agents may be released from the glove according to the present invention. For instance, in some embodiments, the active agent may be a skin-conditioner that improves moisture retention, softness, texture, and other properties of the skin. One example of such a skin-conditioner is an emollient that helps restore dry skin to a more normal moisture balance. Specifically, emollients act on the skin by supplying fats and oils that blend with skin, making it pliable, repairing some of the cracks and fissures in the stratum corneum, and forming a protective film that traps water in the skin. Emollients that may be suitable for use in the present invention include, but are not limited to, beeswax, butyl stearate, ceramides, cetyl palmitate, eucerit, isohexadecane, isopropyl palmitate, isopropyl myristate, mink oil, mineral oil, nut oil, oleyl alcohol, petroleum jelly or petrolatum, glyceral stearate, avocado oil, jojoba oil, lanolin (or woolwax), lanolin derivatives such as lanolin alcohol, retinyl palmitate (a vitamin A derivative), cetearyl alcohol, squalane, squalene, stearic acid, stearyl alcohol, myristal myristate, various lipids, decyl oleate and castor oil. Another possible skin conditioner is a humectant, which may supply the skin with water by attracting moisture from the air and holding it on the skin. Humectants that may be suitable in the present invention include, but are not limited to, alanine, glycerin, polyethylene glycol, propylene glycol, butylene glycol, hyaluronic acid, Natural Moisturizing Factor (a mixture of amino acids and salts that are among the skin's natural humectants), saccharide isomerase, sodium lactate, sorbitol, urea, and so forth. Still other suitable skin-conditioners include antioxidants, a group of substances that prevent or slow the oxidation process of skin, thereby protecting it from premature aging. Exemplary antioxidants include, but are not limited to, Vitamin E, Vitamin E derivatives, Vitamin C, Vitamin C derivatives, Vitamin A palmitate, butylated hydroxy toluene, phenols, phenolic derivatives, thiadipropionate esters, hydroquinone derivatives, alkylated aryl amine,

combinations thereof, and so forth.

The active agent may also be a botanical agent that may potentially reduce swelling, itching, reddening, etc. Examples of some botanicals that may be used include, but are not limited to, Agnus castus, aloe vera, comfrey, calendula, dong quai, black cohosh, chamomile, evening primrose, Hypericum perforatum, licorice root, black currant seed oil, St. John's wort, tea extracts, lemon balm, capsicum, rosemary, Areca catechu, mung bean, borage seed oil, witch hazel, fenugreek, lavender, soy, almonds, chamomile extracts (e.g., bisabolol), elder flowers, honey, safflower oil, and elastin.

The hydrogel coating 26 may be applied to the substrate body 24 using any suitable method. For example, techniques, such as dipping, spraying, patting, tumbling, etc., may be utilized in the present invention. The average thickness of the hydrogel coating 26, when dry, may range from about 0.05 to about 50 micrometers, in some embodiments from about 0.1 to about 20 micrometers, and in some embodiments, from about 1 to about 10 micrometers. Such a thin coating may provide enhanced donning benefits to the glove 20. In addition, the dried hydrogel coating 26 may comprise from about 0.0001 to about 1 gram per gram of the glove, in some embodiments from about 0.001 to about 0.5 grams per gram of the glove, and in some embodiments, from about 0.01 to about 0.2 grams per gram of the glove 20.

As stated above, a lubricant coating 32 may also overly the hydrogel coating 26 to aid in damp donning. The lubricant coating 32 may cover only a portion of the hydrogel coating 26, or cover its entire surface. In the illustrated embodiment, for example, the lubricant coating 32 covers the entire surface of the hydrogel coating 26 and defines a wearer-contacting surface 27 of the glove 20 that contacts the body of the wearer 22 during use. Alternatively, however, the lubricant coating 32 may cover only those portions of the substrate body 30 not already covered by the hydrogel coating 26.

Any of a variety of well-known materials may be used to form the lubricant coating 32. For example, suitable lubricants include silicone emulsions, such as described in U.S. Patent Application Publication No. 2003/0118837 to Modha, et al., which is incorporated herein in its entirety by reference thereto for all purposes. The solids content of the silicone emulsion may be from about 0.1 wt.% to about

10 wt.%, in some embodiments from about 0.25 wt.% to about 5 weight %, and in some embodiments, from about 0.3 wt.% to about 1 wt.%. To lower the solids content of a commercially available silicone emulsion, for example, additional amounts of solvent may be utilized. By varying the solids content, the presence of 5 silicone in the glove 20 may be controlled. For example, to form a glove with a higher degree of donning properties, the silicone emulsion may have a relatively high solids content so that a greater percentage of the silicone is incorporated into the coating 32 during the forming process. The thickness of the lubricant coating 32 may also vary. For example, the thickness may range from about 0.001 10 millimeters to about 0.4 millimeters. In another embodiment, the thickness may range from about 0.01 millimeters to about 0.30 millimeters. In still another embodiment, the thickness may range from about 0.01 millimeters to about 0.20 millimeters.

In one particular embodiment, the silicone emulsion used to form the 15 lubricant coating 32 is DC 365, which is a pre-emulsified silicone (35% solids content) that is commercially available from Dow Corning Corporation (Midland, Michigan) and believed to contain 40-70% water (aqueous solvent), 30-60% methyl- modified polydimethylsiloxane (silicone), 1-5% propylene glycol (non-aqueous solvent), 1-5% polyethylene glycol sorbitan monolaurate (nonionic surfactant), and 1-5% octylphenoxy polyethoxy ethanol (nonionic surfactant). In another embodiment, the silicone emulsion is SM 2140 (50% solids content), which is a pre-emulsified silicone that is commercially available from GE Silicones (Waterford, New York) and believed to contain 30-60% water (aqueous solvent), 20 30-60% amino-modified dimethylpolysiloxane (silicone), 1-5% ethoxylated nonyl phenol (nonionic surfactant), 1-5% trimethyl-4-nonyloxyethoxyethoxy ethanol (nonionic surfactant), and minor percentages of various other components. In still another embodiment, the silicone emulsion is SM 2150 (50% solids content), which is a pre-emulsified silicone that is commercially available from GE Silicones (Waterford, New York) and believed to contain 30-60% water (aqueous solvent), 25 30-60% amino-modified dimethylpolysiloxane (silicone), 1-5% polyoxyethylene lauryl ether, 1-5% a nonionic surfactant, and minor percentages of various other components. If desired, these pre-emulsified silicones may be diluted with water or other solvents prior to use in the lubricant coating 32.

The lubricant coating 32 may also include a cationic surfactant (e.g., cetyl pyridinium chloride), an anionic surfactant (e.g., sodium lauryl sulfate), or a nonionic surfactant. For instance, in one embodiment, the lubricant coating 32 contains a quaternary ammonium compound, such as Varisoft BTMS (available from Goldschmidt Chemical Corp. of Dublin, Ohio) and a silicone emulsion (AF-60) obtained from General Electric Silicone. Varisoft BTMS contains behenyl trimethyl sulfate and cetyl alcohol, while AF-60 contains polydimethylsiloxane, acetylaldehyde, and small percentages of emulsifiers. Various other suitable lubricants are described, for instance, in U.S. Patent Nos. 5,742,943 to Chen and 6,306,514 to Weikel, et al., which are incorporated herein in their entirety by reference thereto for all purposes.

Further, besides the above-mentioned layers, the glove 20 may also contain additional layers if desired. For example, in one embodiment, the gripping surface 30 of the glove 20 contains a silicone emulsion, such as described above, that improves the gripping characteristics of the glove 20 by inhibiting chlorination of the surface 30.

An elastomeric article made in accordance with the present invention may generally be formed using a variety of processes known in the art. In fact, any process capable of making an elastomeric article may be utilized in the present invention. For example, elastomeric article formation techniques may utilize dipping, spraying, chlorination, drying, curing, as well as any other technique known in the art. In this regard, one embodiment of an "on-line" method of dip forming a glove formed from natural rubber latex will now be described in more detail.

Initially, any well-known former, such as formers made from metals, ceramics, or plastics, is provided. Although glove-shaped formers are described herein, it should also be understood that formers having any other shape (e.g., condom-shaped) may be used in accordance with the present invention to form articles having different shapes. The former is dipped into a bath containing a coagulant, a surfactant, water, and optionally other ingredients, such as a salt that contains calcium ions (e.g., calcium nitrate and/or calcium carbonate) to break the protection system of a natural rubber latex emulsion. The salt may also facilitate removal of the tacky latex from the former, thus acting as a release agent. The

surfactant provides good wetting to avoid forming a meniscus and trapping air between the form and deposited latex, particularly in the cuff area. If desired, the former may be preheated so that the residual heat dries off the water leaving, for example, calcium nitrate, calcium carbonate, and surfactant on the surface of the former. Other suitable coagulant solutions are also described in U.S. Patent No. 5 4,310,928 to Joung, which is incorporated herein in its entirety by reference thereto for all purposes.

After being immersed in the coagulant composition, the former is withdrawn and allowed to dry. The former is then dipped into a tank containing a natural rubber latex bath to form the substrate body 24. The bath contains, for example, 10 natural rubber latex, stabilizers, antioxidants, curing activators, organic accelerators, vulcanizers, and so forth. The stabilizers may, for example, be phosphate-type surfactants. The antioxidants may be phenol-based compounds, such as 2,2'-methylenebis (4-methyl-6-t-butylphenol). The curing activator may be zinc oxide. The organic accelerator may be dithiocarbamate. The vulcanizer may be sulfur or a sulfur-containing compound. If these materials are used, the stabilizer, antioxidant, activator, accelerator and vulcanizer may be dispersed into water to avoid crumb formation by using a ball mill. This dispersion is then mixed into the latex. The former is dipped into one or more latex baths a sufficient 15 number of times to build up the desired thickness on the former. By way of example, the substrate body 24 may have a thickness of from about 0.1 to about 0.3 millimeters. A bead roll station may, in some embodiments, be utilized to impart a cuff to the glove 20. The latex-coated former is then dipped into a leaching tank in which hot water is circulated to remove the water-soluble 20 components, such as residual calcium nitrates and proteins contained in the natural latex. This leaching process may continue for about twelve minutes with the tank water being about 49°C.

The coated former may then be dipped one or more times into a solution to 30 form the hydrogel coating 26 of the glove 20. In one embodiment, the former is dipped into an aqueous solution of a water-soluble hydrogel-forming polymer or a mixture of such polymers. The aqueous composition may, for instance, include from about 0.1 wt.% to about 30 wt.% of hydrogel-forming polymer(s), in some embodiments from about 0.5 wt.% to about 10 wt.% of hydrogel-forming

polymer(s), and in some embodiments, from about 1 wt.% to about 5 wt.% of hydrogel-forming polymer(s). The aqueous solution may also contain from about 0.01 wt.% to about 10 wt.% crosslinking agent(s), in some embodiments from about 0.1 wt.% to about 5 wt.% crosslinking agent(s), and in some embodiments, from about 0.2 wt.% to about 2 wt.% crosslinking agent(s). Water typically constitutes from about 70 wt.% to about 99.9 wt.%, and in some embodiments, from about 90 wt.% to about 99 wt.% of the aqueous solution.

The aqueous solution may also contain other components. For example, the solution may also contain an active agent that is releasable from the hydrogel coating 26. The amount of the active employed may vary depending on the type of active agent, the type of hydrogel, etc. Specifically, hydrogels that provide a slow release rate may require a higher active agent content than hydrogels that provide a fast release rate. For example, the aqueous solution may contain from about 0.0001 wt.% to about 30 wt.% of active agent(s), in some embodiments from about 0.001 wt.% to about 10 wt.% active agent(s), and in some embodiments, from about 0.1 wt.% to about 5 wt.% active agent(s). In addition, to initiate or speed up the crosslinking process, a catalyst, such as p-toluene sulfonic acid or hydrochloric acid, may be utilized. Polymerization initiators may also be utilized, such as described in U.S. Patent No. 6,242,042 to Goldstein, et al., which is incorporated herein in its entirety by reference thereto for all purposes. A pH adjuster, such as an acid or base, may be also be added to achieve a certain pH.

Once coated, the former is sent to a curing station (e.g., oven) where the natural rubber is vulcanized and the hydrogel-forming polymer is crosslinked. If desired, the curing station may initially evaporate any remaining water and then proceed to the higher temperature vulcanization and crosslinking steps. For instance, curing of the hydrogel-forming polymer may be initiated by heating at a temperature from about 25°C to about 200°C, in some embodiments from about 50°C to about 150°C, and in some embodiments from about 70°C to about 120°C, for a period of time of from about 1 minute to about 12 hours, in some embodiments from about 5 minutes to about 5 hours, and in some embodiments, from about 10 minutes to about 1 hour. Vulcanization may occur at the same time as the crosslinking of the hydrogel-forming polymer, or at a different time. If desired, the oven may be divided into four different zones with a former being

conveyed through the zones of increasing temperature. One example is an oven having four zones with the first two zones being dedicated to drying, and the second two zones being primarily to vulcanization and crosslinking of the hydrogel polymer. Each of the zones may have a slightly higher temperature, for example, the first zone at about 80°C, the second zone at about 95°C, a third zone at about 105°C, and a final zone at about 115°C. The residence time of the former within a zone may, for instance, be about 10 minutes.

Regardless of the technique used to form the glove 20, it has been discovered that various treatment steps conventionally conducted "off-line" (i.e., after stripping) may be conducted "on-line" in accordance with the present invention. For example, the lubricant coating 32 may be applied to the glove 20 while it is still present on the former. In one particular embodiment, a silicone emulsion is first thoroughly mixed with water using a high shear mixer to achieve a homogeneous solution having the desired solids content. Thereafter, the resulting emulsion is then applied to in a variety of ways without removing the glove 20 from the former. For instance, the silicone emulsion may be sprayed onto the glove 20 using a conventional spray nozzle. Alternatively, the glove 20 may be dipped into a silicone emulsion to form the lubricant coating 32. Once applied with the silicone emulsion, the silicone-coated glove is then dried. For example, in some embodiments, the silicone-coated glove may be dried at a temperature of from about 20°C to about 200°C, in some embodiments from about 30°C to about 150°C, and in some embodiments, from about 35°C to about 115°C. It should be understood that the desired drying temperature may vary widely depending on the polymer(s) used to form the substrate body 24.

In addition to being applied with the lubricant coating 32, the glove 20 may also be halogenated "on-line" while still present on the former. For example, chlorination may be performed by immersing the glove 20 in an aqueous solution containing dissolved chlorine. The concentration of chlorine may be monitored and controlled to control the degree of chlorination. The chlorine concentration is typically at least about 100 parts per million (ppm), in some embodiments from about 200 ppm to about 3500 ppm, and in some embodiments, from about 300 ppm to about 600 ppm, e.g., about 400 ppm. The time duration of the chlorination step may also be controlled to control the degree of chlorination and may range,

for example, from about 1 to about 10 minutes, e.g., 4 minutes. The glove 20 may then be rinsed with tap water at about room temperature. This rinse cycle may be repeated as necessary. Once all water is removed, the glove 20 may be dried to remove excess water. Other chlorination techniques are described in U.S. Patent Nos. 3,411,982 to Kavalir; 3,740,262 to Agostinelli; 3,992,221 to Homsy, et al.; 4,597,108 to Momose; and 4,851,266 to Momose, 5,792,531 to Littleton, et al., which are incorporated herein in their entirety by reference thereto for all purposes.

Thereafter, the glove 20 may be stripped from the former and turned inside out. The hydrogel coating 26 inhibits the tacky substrate body 24 from sticking to itself. Once turned inside out and removed the former, the hydrogel coating 26 and the optional lubricant coating 32 form the wearer-contacting surface 27 of the glove 20. Although often undesired, the glove 20 may optionally be subjected to various "off-line" treatments, such as chlorination and/or lubrication.

The present invention may be better understood with reference to the following example.

EXAMPLE

The ability to form an elastomeric article in accordance with the present invention was demonstrated. Initially, a glove-shaped former was dipped into a dip tank that contained a coagulant composition. Specifically, the coagulant composition contained 15% by weight calcium nitrate, 6 % by weight calcium carbonate, 0.15% surfactant, and water so that the resulting solids content was about 21%. After dipping, the former into the coagulant, it was removed from the coagulant composition and dried a temperature of 115°C. Next, the former was dipped into a compound of natural rubber latex and allowed to air dry. The resulting substrate body was beaded and leached with water. The thickness of the resulting substrate body was 0.27 millimeters.

The glove was then dipped for 5 to 10 seconds in a polyalcohol-based primer (minimum solids content of 20%) available from Delta Polymer Systems Sdn. Bhd. of Selangor, Malaysia under the name "ACTIVE BOND." After drying the primer, the glove was dipped for 5 to 10 seconds into a sequentially mixed solution of water, phosphoric acid, "BYOSYLK", "BYOSYLK" Part B, and "BYOSYLK" Part A. "BYOSYLK" is polyacrylate-based and has a minimum solids content of 10%, while "BYOSYLK" Part B and "BYOSYLK" Part A are polyalcohol-

based and have a minimum solids content of 80% and 11%, respectively. "BYOSYLK", "BYOSYLK" Part B, and "BYOSYLK" Part A are each available from Delta Polymer Systems Sdn. Bhd. of Selangor, Malaysia. The thickness of the resulting hydrogel coating was 2 to 4 micrometers.

5 After being applied with the hydrogel-forming solution, the glove entered a second beading station and was placed in an oven at 130°C to 150°C for 40 to 60 minutes, wherein the hydrogel polymer and the natural rubber polymer composition were cured. The coated former was cooled and dipped into a solution of chlorine (concentration of 50 to 200 ppm) for 5 to 10 seconds to chlorinate the hydrogel. The coated former was then dipped into a tank of tap water, and
10 immersed for 5 to 10 seconds into a silicone emulsion having a solids content of from 0.3 to 1.0 wt.%. The coating was subsequently dried at 100°C to 120° C, and then stripped from the former.

15 While the invention has been described in detail with respect to the specific embodiments thereof, it will be appreciated that those skilled in the art, upon attaining an understanding of the foregoing, may readily conceive of alterations to, variations of, and equivalents to these embodiments. Accordingly, the scope of the present invention should be assessed as that of the appended claims and any equivalents thereto.